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Olga M. Franz
Printed Name

Olga M Franz
Signature

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Janet M. Hock	)
			)
For	:	METHOD OF INCREASING BONE TOUGHNESS AND STIFFNESS AND REDUCING FRACTURES	) Corresponding to:) PCT/US99/18961) Filed: 8/19/99
			)
Docket No.	:	X11965	)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents

Washington, D. C. 20231

Sir:

Prior to examination, please amend the application as follows:

In the Specification

Please amend the specification as follows:

Page 5, line 15, delete text starting with "either" and ending with "compared" and replace with --either 20μg/day PTH or 40μg/day PTH, compared--; and

lines 18 - 19, delete text starting with "either" and ending with "compared" and replace with --either 20μg/day PTH or 40μg/day PTH, compared--.

N.E. Page 47, line 7, change "μg/kg/day" to --μg/day--.

In the Claims

Cancel claims 1-8 (which were filed in the PCT case during a personal interview on July 20, 2000) without prejudice.

Please insert the following new claims.

Claims 1-8 filed on 20 July 2000

~~PROPOSED CLAIMS FOR DISCUSSION~~

~~US Format – Method of Use~~

1. A method for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis, said method comprising

administering to said subject a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months, up to 3 years.

2. The method of claim 1 wherein said human subject is at risk of or has osteoporosis arising from an age-related hypogonadal condition.

3. The method of claim 2 wherein said subject human is a postmenopausal woman.

4. The method of claim 1 wherein said daily dose is 20 μg.

5. The method of claim 1 wherein said daily dose is administered for at least about 24 months.

~~US Format – Article of Manufacture~~

6 4. An article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material, said composition comprising a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid and

said packaging material comprising printed matter which indicates that

said composition is effective for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis when administered to said subject such that said parathyroid hormone is administered

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months, up to 3 years.

~~EPO Format New Use~~

7 ~~1~~. Use of a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone for the manufacture of a medicament for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis,

wherein said medicament is administered to said subject without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months, up to 3 years

8 ~~1~~. Use according to claim 7 ~~of a medicament of claim 1 for the manufacture of an article of manufacture comprising packaging material and~~ wherein said medicament is contained within ~~said~~ a packaging material, ~~said medicament comprising a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid and~~

said packaging material comprising printed matter which indicates that

said medicament is effective for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis when administered to said subject such that said parathyroid hormone is administered

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months up to 3 years.

add A1